K063677
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COOK®

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JAN - 5 2007

510(k) Summary

Name:	Cook Endoscopy
Address:	4900 Bethania Station Road Winston-Salem, NC 27105
Phone:	336-744-0157
Fax:	336-201-5994
Contact Person:	Scottie Fariole, Global Regulatory Affairs Specialist
Date:	December 8, 2006
Trade Name:	Fusion Quattro Extraction Balloon XL
Common Name:	Extraction Balloon
Classification Name:	Catheter, Biliary, Surgical (21 CFR 876.5010, Product Code 78 GCA)
Legally Marketed Devices:	Tri-Ex Extraction Balloon with Multiple Sizing (K040129)
Description of the Device:	The subject extraction balloon represents modifications made to existing extraction balloons currently marketed by Cook Endoscopy. The Fusion Quattro Extraction Balloon XL is supplied sterile and intended for single use only.
Intended Use:	Used for endoscopic removal of stones in the biliary system and for contrast injection.
Comparison of Characteristics:	We believe the proposed device to be substantially equivalent to currently marketed predicate device as cleared by K040129.
Performance Data:	We believe risks associated with the modifications to the subject device to be adequately addressed through our Design Control Process. We believe the proposed device to be substantially equivalent to the named predicate in terms of Intended Use, performance characteristics tested and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JAN 0 5 2007

Ms. Scottie Fariole
Global Regulatory Affairs Specialist
Cook Endoscopy
4900 Bethania Station Road
WINSTON-SALEM NC 27105

Re: K063677
Trade/Device Name: Modified Fusion Quattro Extraction Balloon XL
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and Accessories
Regulatory Class: II
Product Code: GCA
Dated: December 8, 2006
Received: December 11, 2006

Dear Ms. Fariole:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063677

Device Name: Fusion Quattro Extraction Balloon XL

Indications for Use:

Used for endoscopic removal of stones in the biliary system and for contrast injection.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagorio

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063677